CLAIMS

1. A polypeptide comprising an immunogenic portion of a native WT1, or a variant thereof that differs in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with WT1-specific antisera and/or T-cell lines or clones is not substantially diminished, wherein the polypeptide comprises no more than 16 consecutive amino acid residues present within a native WT1 polypeptide.

2. A polypeptide according to claim 1, wherein the immunogenic portion binds to an MHC class I molecule.

3. A polypeptide according to claim 1, wherein the immunogenic portion binds to an MHC class II molecule.

4. A polypeptide according to claim 1, wherein the polypeptide comprises a sequence selected from the group consisting of:

(a) sequences recited in one or more of Tables II - XLVI;

(b) variants of the foregoing sequences that differ in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antisera and/or T-cell lines or clones is not substantially diminished; and

(c) mimetics of the foregoing sequences, wherein the ability of the mimetic to react with antigen-specific antisera and/or T-cell lines or clones is not substantially diminished.

5. A polypeptide according to claim 1, wherein the polypeptide comprises a sequence selected from the group consisting of:

(a) ALLPAVPSL (SEQ ID NO:34), GATLKGVAA (SEQ ID NO:88), CMTWNQMNL (SEQ ID NOs: 49 and 258), SCLESQPTI (SEQ ID NOs: 199 and 296), SCLESQPAI (SEQ ID NO:198), NLYQMTSQL (SEQ ID NOs: 147 and 284); ALLPAVSSL (SEQ ID NOs: 35 and 255), RMFPNAPYL (SEQ ID NOs: 185 and 293);

(b) variants of the foregoing sequences that differ in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antisera and/or T-cell lines or clones is not substantially diminished; and

(c) mimetics of the foregoing sequences, wherein the ability of the mimetic to react with antigen-specific antisera and/or T-cell lines or clones is not substantially diminished.

6. A polypeptide according to claim 1, wherein the polypeptide comprises 4-16 consecutive amino acids of a native WT1 polypeptide.

7. A polypeptide according to claim 1, wherein the polypeptide comprises 8-10 consecutive amino acids of a native WT1 polypeptide.

8. A polypeptide comprising an immunogenic portion of amino acid residues 1 - 174 of a native WT1 polypeptide, or a variant thereof that differs in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with WT1-specific T-cell lines or clones is not substantially diminished, wherein the polypeptide comprises no more than 16 consecutive amino acid residues present within amino acids 175 to 449 of the native WT1 polypeptide.

9. A polypeptide comprising a variant of an immunogenic portion of WT1 that differs in substitutions at between 1 and 3 amino acid positions within the immunogenic portion, such that the ability of the variant to react with WT1-specific antisera and/or T-cell lines or clones is enhanced relative to a native WT1.

10. A mimetic of an immunogenic portion of a WT1 polypeptide, wherein at least one amino acid residue is replaced by a compound that is not an amino acid, such that the ability of the mimetic to react with antigen-specific antisera and/or T-cell lines or clones is not diminished.

11. A pharmaceutical composition comprising a polypeptide according to claim 1, in combination with a pharmaceutically acceptable carrier or excipient.

12. A pharmaceutical composition according to claim 11, wherein the polypeptide comprises 4-16 consecutive amino acids of a native WT1 polypeptide.

13. A pharmaceutical composition according to claim 11, wherein the polypeptide comprises 8-16 consecutive amino acids of a native WT1 polypeptide.

14. A pharmaceutical composition comprising a polypeptide according to claim 8, in combination with a pharmaceutically acceptable carrier or excipient.

15. A vaccine comprising a polypeptide according to claim 1, in combination with a non-specific immune response enhancer.

16. A vaccine according to claim 15, wherein the polypeptide comprises 4-16 consecutive amino acids of a native WT1 polypeptide.

17. A vaccine according to claim 15, wherein the polypeptide comprises 8-10 consecutive amino acids of a native WT1 polypeptide.

18. A vaccine according to claim 15, wherein the immune response enhancer is an adjuvant.

19. A vaccine comprising a polypeptide according to claim 8, in combination with a non-specific immune response enhancer.

20. A vaccine according to claim 19, wherein the immune response enhancer is an adjuvant.

21. A vaccine comprising:

(a) a WT1 polypeptide, wherein the polypeptide comprises an immunogenic portion of a native WT1 or a variant thereof that differs in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific T cell lines or clones is not substantially diminished; and

(b) a non-specific immune response enhancer that preferentially enhances a T cell response in a patient.

22. A vaccine according to claim 21, wherein the immune response enhancer is selected from the group consisting of Montanide ISA50, Seppic MONTANIDE ISA 720, cytokines (*e.g.*, GM-CSF, Flat3-ligand), microspheres, dimethyl dioctadecyl ammoniumbromide (DDA) based adjuvants, AS-1, AS-2, Ribi Adjuvant system based adjuvants, QS21, saponin based adjuvants, Syntex adjuvant in its microfluidized form, MV, ddMV, immune stimulating complex (iscom) based adjuvants and inactivated toxins.

23. A pharmaceutical composition comprising a mimetic according to claim 10, in combination with a pharmaceutically acceptable carrier or excipient.

24. A vaccine comprising a mimetic according to claim 10, in combination with a non-specific immune response enhancer.

25. A polynucleotide encoding a polypeptide according to claim 1 or claim 8.

26. A pharmaceutical composition, comprising:

(a) a polynucleotide encoding a WT1 polypeptide, wherein the polypeptide comprises an immunogenic portion of a native WT1 or a variant thereof that differs in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antibodies and/or T cell lines or clones is not substantially diminished; and

(b) a pharmaceutically acceptable carrier or excipient.

27. A pharmaceutical composition, comprising:

(a) an antibody or antigen-binding fragment thereof that specifically binds to a WT1 polypeptide; and

(b) a pharmaceutically acceptable carrier or excipient.

28. A pharmaceutical composition, comprising:

(a) a T cell that specifically reacts with a WT1 polypeptide; and

(b) a pharmaceutically acceptable carrier or excipient.

29. A pharmaceutical composition, comprising:

(a) an antigen presenting cell that expresses

(i) a WT1 polypeptide that comprises an immunogenic portion of a native WT1 or a variant thereof that differs in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antibodies and/or T cell lines or clones is not substantially diminished; and

(b) a pharmaceutically acceptable carrier or excipient.

30. A vaccine, comprising:

(a) a polynucleotide encoding a WT1 polypeptide, wherein the polypeptide comprises an immunogenic portion of a native WT1 or a variant thereof that differs in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antibodies and/or T cell lines or clones is not substantially diminished; and

(b) a non-specific immune response enhancer.

31. A vaccine, comprising:

(a) an antigen presenting cell that expresses:

(i) a WT1 polypeptide that comprises an immunogenic portion of a native WT1 or a variant thereof that differs in one or more substitutions, deletions, additions

and/or insertions such that the ability of the variant to react with antigen-specific antibodies and/or T cell lines or clones is not substantially diminished; and

(b) a non-specific immune response enhancer.

32. A vaccine comprising:

(a) an anti-idiotypic antibody or antigen-binding fragment thereof that is specifically bound by an antibody that specifically binds to an immunogenic portion of WT1; and

(b) non-specific immune response enhancer.

33. A vaccine according to any one of claims 30-32, wherein the immune response enhancer is an adjuvant.

34. A vaccine according to any one of claims 30-32, wherein the immune response enhancer preferentially enhances a T cell response in a patient.

35. A method for enhancing or inducing an immune response in a human patient, comprising administering to a patient a pharmaceutical composition comprising:

(a) a WT1 polypeptide that comprises an immunogenic portion of a native WT1 or a variant thereof that differs in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antibodies and/or T cell lines or clones is not substantially diminished; and

(b) a physiologically acceptable carrier or excipient;

and thereby enhancing or inducing an immune response specific for WT1 or a cell expressing WT1 in the human patient.

36. A method for enhancing or inducing an immune response in a patient, comprising administering to a patient a pharmaceutical composition according to any one of claims 11, 14, 23 or 26-29.

37. A method for enhancing or inducing an immune response in a human patient, comprising administering to a patient a vaccine comprising:

(a) a WT1 polypeptide that comprises an immunogenic portion of a native WT1 or a variant thereof that differs in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antibodies and/or T cell lines or clones is not substantially diminished; and

(b) a non-specific immune response enhancer;

and thereby enhancing or inducing an immune response specific for WT1 or a cell expressing WT1 in the human patient.

38. A method for enhancing or inducing an immune response in a patient, comprising administering to a patient a vaccine according to any one of claims 15, 19, 21, 24 or 30-32, and thereby enhancing or inducing an immune response specific for WT1 or a cell expressing WT1 in the patient.

39. A method for inhibiting the development of a malignant disease associated with WT1 expression in a human patient, comprising administering to a human patient a pharmaceutical composition comprising:

(a) a WT1 polypeptide that comprises an immunogenic portion of a native WT1 or a variant thereof that differs in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antibodies and/or T cell lines or clones is not substantially diminished; and

(b) a physiologically acceptable carrier or excipient;

and thereby inhibiting the development of a malignant disease associated with WT1 expression in the human patient.

40. A method for inhibiting the development of a malignant disease associated with WT1 expression in a patient, comprising administering to a patient a pharmaceutical composition according to any one of claims 11, 14, 23 or 26-29, and thereby inhibiting the development of a malignant disease in the patient.

41. A method for inhibiting the development of a malignant disease associated with WT1 expression in a human patient, comprising administering to a patient a vaccine comprising:

(a) a WT1 polypeptide that comprises an immunogenic portion of a native WT1 or a variant thereof that differs in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antibodies and/or T cell lines or clones is not substantially diminished; and

(b) a non-specific immune response enhancer;

and thereby inhibiting the development of a malignant disease in the patient.

42. A method for inhibiting the development of a malignant disease associated with WT1 expression in a patient, comprising administering to a patient a vaccine according to any one of claims 15, 19, 21, 24 or 30-32, and thereby inhibiting the development of a malignant disease in the patient.

43. A method according to claim 39 or claim 41, wherein the malignant disease is a leukemia.

44. A method according to claim 43, wherein the leukemia is acute myeloid leukemia, acute lymphocytic leukemia or chronic myeloid leukemia.

45. A method according to claim 39 or claim 41, wherein the malignant disease is a cancer.

46. A method according to claim 45, wherein the cancer is breast, lung, thyroid or gastrointestinal cancer or a melanoma.

47. A method according to claim 40, wherein the malignant disease is a leukemia.

48. A method according to claim 47, wherein the leukemia is acute myeloid leukemia, acute lymphocytic leukemia or chronic myeloid leukemia.

49. A method according to claim 40, wherein the malignant disease is a cancer.

50. A method according to claim 49, wherein the cancer is breast, lung, thyroid or gastrointestinal cancer or a melanoma.

51. A method according to claim 42, wherein the malignant disease is a leukemia.

52. A method according to claim 51, wherein the leukemia is acute myeloid leukemia, acute lymphocytic leukemia or chronic myeloid leukemia.

53. A method according to claim 42, wherein the malignant disease is a cancer.

54. A method according to claim 53, wherein the cancer is breast, lung, thyroid or gastrointestinal cancer or a melanoma.

55. A method according to claim 39, wherein the pharmaceutical composition comprises a WT1 polypeptide that comprises a sequence selected from the group consisting of sequences recited in one or more of Tables II - XLVI and variants of the foregoing sequences that differ in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antisera and/or T-cell lines or clones is not diminished.

56. A method according to claim 39, wherein the pharmaceutical composition comprises a WT1 polypeptide that comprises a sequence selected from the group consisting of ALLPAVPSL (SEQ ID NO:34), GATLKGVAA (SEQ ID NO:88),

CMTWNQMNL (SEQ ID NOs: 49 and 258), SCLESQPTI (SEQ ID NOs: 199 and 296), SCLESQPAI (SEQ ID NO:198), NLYQMTSQL (SEQ ID NOs: 147 and 284), ALLPAVSSL (SEQ ID NOs: 35 and 255); RMFPNAPYL (SEQ ID NOs: 185 and 293) and variants of the foregoing sequences that differ in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antisera and/or T-cell lines or clones is not diminished.

57. A method according to claim 41, wherein the vaccine comprises a WT1 polypeptide that comprises a sequence selected from the group consisting of sequences recited in one or more of Tables II - XLVI and variants of the foregoing sequences that differ in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antisera and/or T-cell lines or clones is not diminished.

58. A method according to claim 41, wherein the vaccine comprises a WT1 polypeptide that comprises a sequence selected from the group consisting of ALLPAVPSL (SEQ ID NO:34), GATLKGVAA (SEQ ID NO:88), CMTWNQMNL (SEQ ID NOs: 49 and 258), SCLESQPTI (SEQ ID NOs: 199 and 296), SCLESQPAI (SEQ ID NO:198), NLYQMTSQL (SEQ ID NOs: 147 and 284), ALLPAVSSL (SEQ ID NOs: 35 and 255), RMFPNAPYL (SEQ ID NOs: 185 and 293) and variants of the foregoing sequences that differ in one or more substitutions, deletions, additions and/or insertions such that the ability of the variant to react with antigen-specific antisera and/or T-cell lines or clones is not diminished.

59. A method for removing cells expressing WT1 from bone marrow, peripheral blood, or a fraction of bone marrow or peripheral blood, comprising contacting bone marrow, peripheral blood or a fraction of bone marrow or peripheral blood with T cells that specifically react with a WT1 polypeptide, wherein the step of contacting is performed under conditions and for a time sufficient to permit the removal of WT1 positive cells to less than 10% of the number of myeloid or lymphatic cells in the bone marrow, peripheral blood or a fraction of bone marrow or peripheral blood.

60. A method for inhibiting the development of a malignant disease associated with WT1 expression in a patient, comprising administering to a patient bone marrow, peripheral blood or a fraction or bone marrow or peripheral blood prepared according to the method of claim 59.

61. A method according to claim 60, wherein the bone marrow, peripheral blood or fraction is autologous.

62. A method according to claim 60, wherein the bone marrow, peripheral blood or fraction is syngeneic or allogeneic.

63. A method for stimulating and/or expanding T cells, comprising contacting T cells with a WT1 polypeptide, a polynucleotide encoding a WT1 polypeptide and/or an antigen presenting cell that expresses a WT1 polypeptide under conditions and for a time sufficient to permit the stimulation and/or expansion of T cells.

64. A method according to claim 63, wherein the T cells are present within bone marrow, peripheral blood or a fraction of bone marrow or peripheral blood.

65. A method according to claim 63, wherein the bone marrow, peripheral blood or fraction is obtained from a patient afflicted with a malignant disease associated with WT1 expression.

66. A method according to claim 63, wherein the bone marrow, peripheral blood or fraction is obtained from a mammal that is not afflicted with a malignant disease associated with WT1 expression.

67. A method according to claim 63, wherein the T cells are cloned prior to expansion.

68. A method for stimulating and/or expanding T cells in a mammal, comprising administering to a mammal a pharmaceutical composition comprising:

(a) one or more of:

(i) a WT1 polypeptide;

(ii) a polynucleotide encoding a WT1 polypeptide; or

(iii) an antigen-presenting cell that expresses a WT1 polypeptide; and

(b) a physiologically acceptable carrier or excipient;

and thereby stimulating and/or expanding T cells in a mammal.

69. A method for stimulating and/or expanding T cells in a mammal, comprising administering to a mammal a vaccine comprising:

(a) one or more of:

(i) a WT1 polypeptide;

(ii) a polynucleotide encoding a WT1 polypeptide; or

(iii) an antigen-presenting cell that expresses a WT1 polypeptide; and

(b) a non-specific immune response enhancer;

and thereby stimulating and/or expanding T cells in a mammal.

70. A method for inhibiting the development of a malignant disease associated with WT1 expression in a patient, comprising administering to a patient T cells prepared according to the method of claim 63.

71. A method according to claim 70, wherein the bone marrow, peripheral blood or fraction is obtained from a patient afflicted with a malignant disease associated with WT1 expression.

72. A method according to claim 70, wherein the bone marrow, peripheral blood or fraction is obtained from a mammal that is not afflicted with a malignant disease associated with WT1 expression.

73. A method for monitoring the effectiveness of an immunization or therapy for a malignant disease associated with WT1 expression in a patient, comprising the steps of:

(a) incubating a first biological sample with one or more of:

(i) a WT1 polypeptide;

(ii) a polynucleotide encoding a WT1 polypeptide; or

(iii) an antigen-presenting cell that expresses a WT1 polypeptide

wherein the first biological sample is obtained from a patient prior to a therapy or immunization, and wherein the incubation is performed under conditions and for a time sufficient to allow immunocomplexes to form;

(b) detecting immunocomplexes formed between the WT1 polypeptide and antibodies in the biological sample that specifically bind to the WT1 polypeptide;

(c) repeating steps (a) and (b) using a second biological sample obtained from the patient following therapy or immunization; and

(d) comparing the number of immunocomplexes detected in the first and second biological samples, and therefrom monitoring the effectiveness of the therapy or immunization in the patient.

74. A method according to claim 73, wherein the step of detecting comprises (a) incubating the immunocomplexes with a detection reagent that is capable of binding to the immunocomplexes, wherein the detection reagent comprises a reporter group, (b) removing unbound detection reagent, and (c) detecting the presence or absence of the reporter group.

75. A method according to claim 74, wherein the detection reagent comprises a second antibody, or antigen-binding fragment thereof, capable of binding to the antibodies that specifically bind to the WT1 polypeptide.

76. A method according to claim 74, wherein the detection reagent comprises Protein A.

77. A method according to claim 74, wherein the reporter group is selected from the group consisting of radioisotopes, fluorescent groups, luminescent groups, enzymes, biotin and dye particles.

78. A method according to claim 73 wherein a reporter group is bound to the WT1 polypeptide, and wherein the step of detecting comprises removing unbound WT1 polypeptide and subsequently detecting the presence or absence of the reporter group.

79. A method for monitoring the effectiveness of an immunization or therapy for a malignant disease associated with WT1 expression in a patient, comprising the steps of:

(a) incubating a first biological sample with one or more of:

(i) a WT1 polypeptide;

(ii) a WT1 polynucleotide encoding a WT1 polypeptide; or

(iii) an antigen-presenting cell that expresses a WT1 polypeptide;

wherein the biological sample comprises CD4+ and/or CD8+ T cells and is obtained from a patient prior to a therapy or immunization, and wherein the incubation is performed under conditions and for a time sufficient to allow specific activation, proliferation and/or lysis of T cells;

(b) detecting an amount of activation, proliferation and/or lysis of the T cells;

(c) repeating steps (a) and (b) using a second biological sample comprising CD4+ and/or CD8+ T cells, wherein the second biological sample is obtained from the same patient following therapy or immunization; and

(d) comparing the amount of activation, proliferation and/or lysis of T cells in the first and second biological samples, and therefrom monitoring the effectiveness of the therapy or immunization in the patient.

80. A method according to claim 73 or claim 79, wherein the malignant disease is a cancer or a leukemia.

81. A method for inhibiting the development of a malignant disease associated with WT1 expression in a patient, comprising the steps of:

(a) incubating $CD4^+$ T cells isolated from a patient with one or more of:

(i) a WT1 polypeptide;

(ii) a polynucleotide encoding a WT1 polypeptide; or

(iii) an antigen presenting cell that expresses a WT1 polypeptide;

such that the T cells proliferate; and

(b) administering to the patient an effective amount of the proliferated T cells, and therefrom inhibiting the development of a malignant disease in the patient.

82. A method according to claim 81, wherein the malignant disease is a cancer or a leukemia.

83. A method according to claim 81, wherein the step of incubating the T cells is repeated one or more times.

84. A method for inhibiting the development of a malignant disease associated with WT1 expression in a patient, comprising the steps of:

(a) incubating $CD4^+$ T cells isolated from a patient with one or more of:

(i) a WT1 polypeptide;

(ii) a polynucleotide encoding a WT1 polypeptide; or

(iii) an antigen presenting cell that expresses a WT1 polypeptide;

such that the T cells proliferate;

(b) cloning one or more cells that proliferated in the presence of WT1 polypeptide; and

(c) administering to the patient an effective amount of the cloned T cells.

85. A method according to claim 84, wherein the malignant disease is a cancer or a leukemia.

86. A method for inhibiting the development of a malignant disease associated with WT1 expression in a patient, comprising the steps of:

(a) incubating $CD8^+$ T cells isolated from a patient with one or more of:

(i) a WT1 polypeptide;

(ii) a polynucleotide encoding a WT1 polypeptide; or

(iii) an antigen presenting cell expressing a WT1 polypeptide;

such that the T cells proliferate; and

(b) administering to the patient an effective amount of the proliferated T cells, and therefrom inhibiting the development of a malignant disease in the patient.

87. A method according to claim 86, wherein the malignant disease is a cancer or a leukemia.

88. A method according to claim 86, wherein the step of incubating the T cells is repeated one or more times.

89. A method for inhibiting the development of a malignant disease associated with WT1 expression in a patient, comprising the steps of:

(a) incubating $CD8^+$ T cells isolated from a patient with one or more of:

(i) a WT1 polypeptide

(ii) a polynucleotide encoding a WT1 polypeptide; or

(iii) an antigen presenting cell that expresses a WT1 polypeptide;

such that the T cells proliferate;

(b) cloning one or more cells that proliferated in the presence of WT1 polypeptide; and

(c) administering to the patient an effective amount of the cloned T cells.

90. A method according to claim 89, wherein the malignant disease is a cancer or a leukemia.

91. A method for determining the presence or absence of a malignant disease associated with WT1 expression in a patient, comprising the steps of:

(a) incubating $CD4^+$ T cells isolated from a patient with one or more of:

(i) a WT1 polypeptide;

(ii) a polynucleotide encoding a WT1 polypeptide; or

(iii) an antigen presenting cell that expresses a WT1 polypeptide;

and

(b) detecting the presence or absence of specific activation of the T cells, therefrom determining the presence or absence of a malignant disease associated with WT1 expression.

92. A method according to claim 91, wherein the malignant disease is a cancer or a leukemia.

93. A method according to claim 91, wherein the step of detecting comprises detecting the presence or absence of proliferation of the T cells.

94. A method for determining the presence or absence of a malignant disease associated with WT1 expression in a patient, comprising the steps of:

(a) incubating $CD8^+$ T cells isolated from a patient with a one or more of:

(i) a WT1 polypeptide;

(ii) a polynucleotide encoding a WT1 polypeptide; or

(iii) an antigen presenting cell that expresses a WT1 polypeptide; and

(b) detecting the presence or absence of specific activation of the T cells, thereby determining the presence or absence of a malignant disease associated with WT1 expression.

95. A method according to claim 94, wherein the malignant disease is a cancer or a leukemia.

96. A method according to claim 94 wherein the step of detecting comprises detecting the presence or absence of generation of cytolytic activity.

97. A method for determining the presence or absence of a malignant disease associated with WT1 expression in a patient, comprising the steps of:

(a) incubating a biological sample obtained from a patient with one or more of:

(i) a WT1 polypeptide;

(ii) a polynucleotide encoding a WT1 polypeptide; or

(iii) an antigen presenting cell that expresses a WT1 polypeptide;

wherein the incubation is performed under conditions and for a time sufficient to allow immunocomplexes to form; and

(b) detecting immunocomplexes formed between the WT1 polypeptide and antibodies in the biological sample that specifically bind to the WT1 polypeptide; and therefrom determining the presence or absence of a malignant disease associated with WT1 expression.

98. A method according to claim 97, wherein the malignant disease is a cancer or a leukemia.

99. A method according to claim 97, wherein the step of detecting comprises (a) incubating the immunocomplexes with a detection reagent that is capable of binding to the immunocomplexes, wherein the detection reagent comprises a reporter group, (b) removing unbound detection reagent, and (c) detecting the presence or absence of the reporter group.

100. A method according to claim 99, wherein the detection reagent comprises a second antibody, or antigen-binding fragment thereof, capable of binding to the antibodies that specifically bind to the WT1 polypeptide.

101. A method according to claim 99, wherein the detection reagent comprises Protein A.

102. A method according to claim 99, wherein the reporter group is selected from the group consisting of radioisotopes, fluorescent groups, luminescent groups, enzymes, biotin and dye particles.

103. A method according to claim 97 wherein a reporter group is bound to the WT1 polypeptide, and wherein the step of detecting comprises removing unbound WT1 polypeptide and subsequently detecting the presence or absence of the reporter group.